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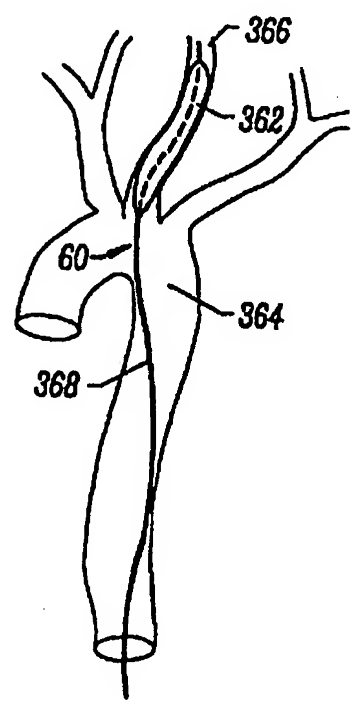
(54) Title: METHODS AND APPARATUS FOR REGIONAL AND WHOLE BODY TEMPERATURE MODIFICATION

(57) Abstract

This invention is methods, and apparatus for temperature modification of selected body regions including an induced state of local hyperthermia of the brain region for neuro-protection. A heat exchange catheter (360) is provided with heat transfer fins (362) projecting or extending outward from the catheter which may be inserted into selected blood vessels or body regions to transfer heat with blood or fluid in the selected blood vessels or body regions. Another aspect of the invention further provides methods, and apparatus for controlling the internal body temperature of a patient. By selectively heating or cooling a portion of the catheter (360) lying within a blood vessel, heat may be transferred to or from blood flowing within the vessel to increase or decrease whole body temperature or temperature of a target region. The catheter (360) may be used alone or in conjunction with other heat exchangers to cool one region of a patient's body while heating another.



lower the temperature of the target tissue, or in the case of whole body hypothermia, to remove more heat than is generated by the body. In removal of heat, the power required to cool the heat exchanger will be largely dependent on the efficiency of the cooling device including the dissipation of excess heat from the device to the environment.

The above estimate does not allow for power losses between the power supply and whatever warming means is utilized. Such losses could include resistance losses in electrical transmission lines between the power supply and a resistance heating element, inherent inefficiencies and other losses in a system having a laser and a diffusing tip, heat losses along a thermally conductive shaft or fluid circulation lumen, and the like. Any such losses which do occur will need to be compensated for by additional power supply capacity. Furthermore, it would be undesirable to limit the performance of a catheter according to the present invention by limiting the size of the power supply used. It would be preferable instead to use a power supply capable of providing power considerably in excess of that actually needed and then controlling the delivery of that power according to the measured temperature of the catheter itself. As mentioned previously, this can be readily accomplished by including a sensitive temperature sensor within the body of the catheter. Nevertheless, the above calculation can be used as a useful estimate of the likely lower bound for sizing a power supply for use in a catheter according to the present invention.

An alternative estimate can be made by comparing the likely performance of the various embodiments described herein with the power requirements for the external blood warming apparatus presently known. Such external warming apparatus generally requires a supply of power on the order of

1000 - 1500 watts and sometimes more. A device formed in accordance with the present invention may require considerably less power than that. First, the present invention may not require an external pump to circulate the blood; this function is provided by the patient's own heart. Accordingly, no power is needed to drive such a pump. Secondly, the present invention may be considerably less complicated than external blood warming systems. Known systems circulate the blood over a relatively lengthy path from the patient, through the warming element, and back into the patient. More heat may be lost over this lengthy path than in devices described herein. Thus, the power required by external blood circulation and warming systems of the type previously known can be used as a rough estimate of the likely upper limit for power required by a system according to the present invention. It is most likely that such a system may be equipped with a power supply having a capacity somewhere between the two rough estimates described above. It is therefore contemplated that a suitable power supply will be capable of providing peak power somewhere in the range between 100 and 1500 watts, probably being in the range between 300 and 1000 watts. The ranges specified are an estimate of suitable peak power capability. The power supply will most commonly be thermostatically controlled in response to a temperature sensor in the body of the catheter. The actual effective power transmitted to the patient will therefore typically be much less than the peak power capacity of the system power supply.

The above calculations refer primarily to a system for heating the blood. With respect to a catheter for cooling the blood, the temperature and power constraints may not be as limiting. Care should be taken to avoid freezing the blood or inducing shock to the patient from excessively rapid cooling. The

primary component of blood is essentially water with a number of suspended and dissolved substances. As such, its freezing point is somewhat below 0°C. However, a catheter adapted to cool blood in a hyperthermic patient or to induce an artificial hypothermia will usually not be operated at temperatures that low. It is presently contemplated that the external surface of such a catheter may be held in the range between about 1°C and 20°C, although the actual temperature could vary between about 0°C and the patient's current body temperature. Additionally, for example, of the case of a heat exchange balloon of some length, the surface temperature of the balloon may vary along its length as it gives off heat to the blood. A balloon may vary in temperature as much as 12°C or more along its length.

Another aspect of the present invention further provides methods for both raising the body temperature of initially hypothermic patients and lowering the body temperature of patients who are initially hyperthermic, or for whom the body temperature is to be lowered below normal for some other purpose. In such cases, it is generally necessary to monitor the target tissue (which in whole body hypothermia may be the whole body and in regional may be, for example, the brain) and control the cooling so the desired temperature will not be exceeded for example, by the physiologic response of the patient. In such cases, this aspect of the invention specifically provides for reversing the heat transfer process to maintain the target tissue at the selected temperature.

As set forth in Fig. 5, a sample control scheme is provided herein for either warming or cooling target tissue to a preferred temperature and maintaining the tissue at about the preferred temperature. The control scheme is described by the flow chart shown in Fig. 5 and illustrated with the graph shown

in Fig. 6. A preferred temperature is pre-selected for the target temperature, for example a temperature of 31°C for the brain tissue. This pre-selected temperature is communicated to a control unit, for example by setting a desired temperature on a control unit for a heat exchange catheter. A heat exchange catheter capable of either removing heat from the blood or adding heat to the blood is inserted so that it is in heat exchange proximity with blood in a blood vessel that delivers blood to a target location such as the brain. The catheter is controlled by the control unit described above that may turn the heat exchanger off or on and may control the heat exchanger to heat or cool the blood which is in heat exchange proximity with the heat exchanger.

The temperature of the brain is monitored, for example by a temperature probe inserted into the brain tissue or by measuring temperature at some proxy location such as the tympanic membrane or nasal cavity provides a temperature measurement that represents the brain temperature. This results in a sensed temperature measurement that is communicated to the controller. An upper variance set point is determined, for example ½ degree above the pre-selected temperature, and communicated to the controller. In this example, that would result in an upper variance set point of 31½°. A lower variance set point is also determined and communicated to the controller, for example ½ degree below the pre-selected temperature, resulting in this example in a lower variance set point of 30½°.

When the heat exchanger is cooling, the sensed temperature of the target tissue is compared with the pre-selected temperature. If the sensed temperature is above the pre-selected temperature, the cooling continues. If the sensed temperature falls to the pre-selected temperature or below, then the controller